Serial No.: 10/777,802
Group Art Unit 1615
Examiner Hasan S. Ahmed

REMARKS

Claims 1-26 are pending in the application. Claims 4-16, 20, 24, and 26 were withdrawn pursuant to a restriction requirement. Thus, claims 1-3, 17-19, 21-23 and 25 are presently under examination. Applicant hereby amends claim 1. Support for the amendment to claim 1 is found *inter alia*, in paragraphs [0032], [0033], [0050] of the specification and the claims as originally filed. Applicant states that there is no issue of new matter.

Rejection Under 35 U.S.C. § 102(a)

In the Office Action, the Examiner rejected claims 1, 2, 17, 18, 19, 21, 22, 23, and 25 as being anticipated by Weber (U.S. Pub. No. WO 03/026532). Specifically, the Examiner asserts that Weber discloses a medical article comprising a release region further comprising the polymeric carrier comprising a first polymer, the drug loaded nanoparticles dispersed within the polymeric carrier, and the layered silicate material (phyllosilicate) of instant claim 1.

In response, Applicants respectfully traverse the rejection and their accompanying remarks. Weber does not all of the elements of the claims. The present device of independent claim 1, as amended, is directed to a medical article comprising a release region, said release region comprising (a) a polymeric carrier comprising a first polymer and (b) drug loaded nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising: silicate particles comprising a layered silicate material; and a first therapeutic agent, *wherein the first therapeutic agent is structurally associated with the silicate particles in that the first therapeutic agent occupies inner spaces between adjacent layers of the silicate material of each silicate particle to form a reservoir for the first therapeutic agent.* The method of independent device claim 26 is directed to a method of providing the medical article of amended claim 1 comprising: providing a release-region-forming fluid comprising (a) said first polymer species and (b) said drug loaded nanoparticles; and applying said release-region-forming fluid to a medical article substrate or to a releasable template.

For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198

USPQ 344, 346 (Fed. Cir. 1978). The Weber reference fails as an anticipatory reference because it fails to teach all of the claimed elements of the present invention within the four corners of the reference, *i.e.* Weber does not teach the claimed drug loaded nanoparticles wherein the first therapeutic agent is structurally associated with the silicate particles in that the first therapeutic agent occupies inner spaces between adjacent layers of the silicate material of each silicate particle to form a reservoir for the first therapeutic agent.

In fact, there is no instruction or enabling disclosure in Weber for incorporating a therapeutic agent into a layered silicate material to create the claimed nanoparticle structure, i.e., a structure in which the therapeutic agent is disposed in the interstices between adjacent layers of the layered silicate material. Applicant's specification, in paragraph [0032], teaches the benefit of such a structure: "By associating the therapeutic agent with the silicate particles, each silicate particle becomes a miniature depot for the therapeutic agent." Weber simply does not teach such claimed structure nor even suggest the benefit of such structure. Rather, Weber provides a large listing of "materials suitable for use in the nanoparticles" and mentions as part of this list, "synthetic or natural smectic phyllosilicates including clays and micas (that may optionally be intercalated, exfoliated and/or otherwise chemically modified)." (Weber, page 9, lines 4-5).

Given that a requirement claim element is missing, Applicant respectfully submits that Weber fails to anticipate the invention as claimed. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(a) over Weber.

Claim 1 is the sole independent claim, and the above comments apply directly to this claim. All other rejected claims (2-3, 17-19, 21-23 and 25) are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above.

Rejection under 35 U.S.C. §103(a)

In the Office Action, the Examiner rejected claims 1 and 3 as being unpatentable over Weber in view of Hunter et al. (U.S. Pub. No. US 2005/0149175). The Examiner states that Weber teaches a medical article comprising a release region and the disclosed article comprises the polyolefin-polyvinylaromatic block copolymer of instant claim 3. The Examiner states that Weber differs from the instant application in that it does not teach halofuginone as a therapeutic agent.

However, use of halofuginone as a therapeutic agent in vascular medical devices was well known in the art at the time the instant application was filed, as evinced by Hunter.

In response, Applicant respectfully traverses the rejection and its supporting remarks. Given the amendments to independent claim 1 (claims 1 and 3 having been rejected), Applicant states that the rejection fails at least because of the fundamental defects discussed above with respect to the anticipation rejection of claim 1 discussed above and these defects are not remedied by the secondary reference (Hunter).

Neither Weber nor Hunter teaches any type of structure for drug loaded nanoparticles made of a layered silicate material and a therapeutic agent. As discussed above, Weber provides no teaching or suggestion for the claimed nanoparticle structure. Hunter et al. provides no discussion or disclosure of nanoparticles whatsoever and thus, fails to address any deficiency in Weber. As the combination of Weber and Hunter et al. fails to meet the threshold for establishing a *prima facie* case of obviousness, Applicant respectfully requests the Examiner to reconsider and to withdraw the rejection of claims 1 and 3 as unpatentable over Weber in view of Hunter et al.

FEES

The Examiner is authorized to charge the petition fee for a three-month extension of time and any other fees deemed to be due or to credit any overpayment for this application to Deposit Account Number 50-1047.

Respectfully submitted,

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